Docket No.: BROAD.028A Customer No. 20,995

INFORMATION DISCLOSURE STATEMENT

Applicant : Larry Eugene West

App. No : 10/723,168

Filed: November 26, 2003

For : INTEGRATED BIO-REACTOR

MONITOR AND CONTROL SYSTEM

Examiner : Bowers, Nathan Andrew

Art Unit : 1797

CERTIFICATE OF EFS WEB TRANSMISSION

I hereby certify that this correspondence, and any other attachment noted on the automated Acknowledgement Receipt, is being transmitted from within the Pacific Time zone to the Commissioner for Patents via the EFS Web server on:

May 2, 2008

(Date)

Joseph M. Reisman, Reg. No. 42,878

Mail Stop Amendment Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Dear Sir:

Enclosed for filing in the above-identified application is a PTO/SB/08 Equivalent listing eight (8) references to be considered by the Examiner. Also enclosed are the eight (8) non-patent references as listed on the Information Disclosure Statement.

I. INTRODUCTION AND SUMMARY OF IDS

This IDS is being filed in U.S. Patent Application No. 10/723,168, entitled "Integrated Bio-Reactor Monitor and Control System" filed November 26, 2003, and in related U.S. Patent Application No. 11/057,079, entitled "Integrated Bio-Reactor Monitor and Control System" filed February 10, 2005 (hereinafter collectively referred to as the "BJC Applications"). The '079 application is a continuation-in-part of the '168 application, and both of these applications are assigned to Broadley-James Corporation ("BJC"). The BJC Applications disclose, *inter alia*, apparatuses and methods generally related to BJC's BioNet[®] Bioreactor Control System ("BioNet[®]").

Charles Crompton, counsel for Finesse and Mr. Mantha, recently provided materials to the undersigned that included declarations from Michael W. Mantha ("Mantha") and Randy Warren ("Warren"). The undersigned understands that, at the time these declarations were

executed, Mantha and Warren were associated with Finesse as consultants or as employees. Finesse, a competitor of BJC, asserts these declarations support its position that Mantha is an unnamed inventor of the BJC Applications. Finesse has provided material of this nature to the undersigned in the past, as described below. BJC has submitted all such material in

Information Disclosure Statements for the BJC Applications.

The new Mantha and Warren Declarations contain allegations (1) accusing BJC of making misrepresentations to the United States Patent and Trademark Office, for example, by failing to submit documents Finesse provided to the undersigned; (2) of Mantha insisting that he has never heard of Stella (BJC's in house bioreactor control project) and denying he knew that BJC was developing a bioreactor control system in 2002; (3) that Mantha's work for Caltrol to build BJC's bioreactor control system prototype supports his inventorship claims; (4) that the BJC Applications do not recite a patentable invention because it can use a commercially available Foundation Fieldbus Interface as one of its networks; and (5) from Warren that purport to support Mantha's inventorship claims.

In this IDS, BJC provides to the USPTO the new declarations and the corresponding referenced exhibits. BJC also provides its analysis of certain allegations contained in the Mantha and Warren Declarations. Some of the allegations and recently provided material (e.g., certain Exhibits to Mantha's Declaration) are duplicative of material previously received from Finesse and previously provided to the USPTO. BJC has already addressed these allegations and material in one or more previously submitted IDS's. Accordingly, only certain issues raised by the Mantha and Warren Declarations will be addressed herein. BJC can, of course, provide additional information on any issue as requested by the USPTO.

II. BACKGROUND AND PRIOR SUBMISSIONS TO THE PTO

Larry West is the sole named inventor on the BJC Applications and, at the time the BJC Applications were filed, was an employee and later an officer of BJC. At BJC, West's responsibilities included sales, marketing and technology development for BioNet[®]. West executed appropriate Inventor's Declarations and Assignments to BJC for each of the BJC Applications. In these documents, West confirmed that he was the sole inventor of all subject matter claimed in the BJC Applications, and assigned his complete right, tile, and interest in the BJC Applications to BJC. These assignments are recorded at Frame/Reel No.

014520/0680 ('168 application) and Frame/Reel No. 015989/0766 ('079 application). This is consistent with all of BJC's documentation and knowledge, and was wholly undisputed until West left BJC to work for BJC's competitor, Finesse, in about October, 2005.

In July, 2006, Charles Crompton, counsel for West (then with Finesse), Finesse, and Mantha, asserted that Finesse had a license to the technology claimed in the BJC Applications from Mantha, an alleged unnamed inventor. As "evidence" of its claims, Finesse produced declarations from West and Mantha that essentially alleged they created BioNet[®] in their spare time and without BJC's involvement, and that BJC only became interested in BioNet[®] after Mantha and West built and presented a prototype for an evaluation/demonstration in March, 2003.¹ On that basis, Finesse took the position that it had obtained a "license" from Mantha to the BJC Applications.

Mantha previously worked for Caltrol, a company that specializes in process automation and control systems. BJC had paid Caltrol to prepare a prototype and manufacture and integrate certain portions of BioNet[®] for BJC. Subsequently, Caltrol has assigned its rights in all of its work-product relating to BioNet[®] to BJC. While working for Caltrol, Mantha participated in assembling a BioNet[®] prototype for BJC. Subsequently, in 2003 and early 2004, while working at AdvanceTech Solutions ("ATS"), Mantha participated in assembling a small number of BioNet[®] products for BJC and did so in accordance with BJC's instructions. Mantha's assembly work ended when BJC decide to move the BioNet[®] assembly process in-house.

1. BJC's October 19, 2006, IDS

On August 1, 2006, Finesse provided documents labeled FI00000049-FI0000269 (referred to herein as the "Mantha Materials") to the undersigned. Those documents generally indicate Mantha was involved in assembling a prototype for BJC. At that time, Finesse alleged that the Mantha Materials establish that Mantha is a co-inventor in BJC's Applications. However, Finesse repeatedly refused to identify what, if any, specific contribution Mr. Mantha allegedly made, explain their reasoning on how they had reached that conclusion, or provide documents contemporaneous with Mr. Mantha's alleged conception of an invention.

¹ See, e.g., West's October 19, 2006, "IDS" submission, Ref. 2 at ¶¶ 3, 6-27; Ref. 3 at ¶¶ 6-16.

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On October 19, 2006, BJC submitted an IDS to the USPTO (hereinafter referred to as the "Oct '06 IDS") that includes correspondence between BJC and Finesse, a complete copy of the (non-confidential) Mantha Materials, and its determination that nothing in the Mantha Materials indicates Mantha was an inventor of any of the claimed subject matter of the BJC Applications. Additional information regarding BJC's analysis of the Mantha Materials is described in the Oct. '06 IDS.

2. West's October 19, 2006, USPTO Submission

On or about October 19, 2006, West provided materials to the USPTO in a submission styled an "IDS" (hereinafter referred to as the "West IDS"). The West IDS includes declarations by West and Mantha, which BJC subsequently submitted in its IDS of May 11, 2007, as Reference 2 and Reference 3. These declarations generally allege that Mantha should be named as a co-inventor, along with West, on the BJC Applications. However, the declarations do not offer any underlying basis or provide corroborating contemporaneous documents that show Mantha's alleged inventorship role.² For instance, they fail to specifically state the alleged contribution Mantha made to the claimed conception of any subject matter of the BJC Applications and when Mantha conceived of the specific subject matter claimed in the BJC Applications. Instead, the declarations essentially state West and Mantha created BioNet® on their own and outside of any work responsibilities or obligations to their employers, that Mantha and West created BioNet® without BJC's involvement, and that BJC "watched from the wings" and had no interest in BioNet[®] until a prototype was assembled and evaluated in about March 2003, at which time BJC claimed ownership of BioNet®.3 BJC submitted evidence to the USPTO in a IDS dated May 11, 2007, (and additional material is submitted herein) that show these allegations are false.

² The undersigned notes that since July, 2006, BJC has repeatedly asked Mr. Mantha to provide documents that directly support his assertions that he created BioNet. Mantha has provided documents that do not support his inventorship claims, but rather generally show he helped assemble BJC's BioNet® prototype. BJC submitted all of these documents that were not confidential (e.g., the Mantha Materials) to the USPTO in the Oct '06 IDS. To date, Mr. Mantha has not provided any contemporaneous documents that support his present day allegations that he conceived of BioNet[®], or rebut BJC's evidence of conceiving and developing BioNet[®]. In fact, Mantha now admits that there are no contemporaneous documents showing his alleged design of BioNet®, or any such BJC documents in his possession, custody, or control. Decl. Mantha dated Oct. 2, 2007 ¶¶ 26, 47, and 48.

³ See West's October 19, 2006, "IDS" submission, Ref. 2 at ¶¶ 3, 6-27; Ref. 3 at ¶¶ 6-16.

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3. BJC's May 11, 2007, IDS

On May 11, 2007, BJC submitted an IDS (the "May '07 IDS") containing analysis and supporting documents that contradicts the assertions made in the West IDS. The documents show that BJC developed BioNet® in a company project called "Stella." In addition, contemporaneous documents submitted by BJC show that West worked on Stella with Scott Broadley and other BJC employees during the exact time period when West had alleged that BJC was not at all involved. Inexplicably, in his declaration West never mentioned Stella or that he had a lead role on BJC's Stella in house project. As explained in the May '07 IDS, BJC conceived of and developed BioNet®, directed Caltrol's work on assembling a BioNet prototype, and paid the invoices for all the BioNet® work provided by Caltrol's employees and consultants. Indeed, the contemporaneous documents clearly illustrate that West's allegations stating otherwise are false. Shortly after BJC provided a copy of the May '07 IDS to Finesse for consideration, the undersigned learned that West was no longer employed by Finesse.

BJC included contemporaneous documents in the May '07 IDS that also illustrate many inaccuracies in a declaration by Mantha which was submitted with the West IDS.⁴ Contrary to Mantha's allegations, in 2002 BJC was developing a bioreactor control system in, and it was BJC that delivered its BioNet[®] prototype to Amgen for a demonstration in March 2003, not Mantha and West.

4. BJC Received New Declarations From Finesse

In a letter dated November 30, 2007 (attached hereto as Reference 1) Charles Crompton provided two new declarations to the undersigned, one from Michael Mantha (dated October 2, 2007, "the Mantha Declaration," attached hereto as Reference 2) and another from Randy Warren (dated October 30, 2007, "the Warren Declaration," attached hereto as Reference 3).⁵ Warren previously worked for BJC on BioNet[®] and was later employed by Finesse, and was apparently so employed at the time he executed his declaration.

⁴ For example, Mantha's assertions that BJC "was not particularly receptive to the idea of developing a bioreactor control and monitor system," that "Mr. West decided to move forward with me in his spare time," that he and West demonstrated "their" prototype to Amgen, and that BJC did not became interested in developing a digitized bioreactor control system until after the Amgen demonstration in March, 2003, were all shown to be false by contemporaneous documents produced by BJC. May '07 IDS Reference 1, Exhibit A ¶¶ 9 and 13.

⁵ The undersigned is informed and believes that since the time that West left Finesse, Mr. Crompton represents only Mantha and Finesse in this matter.

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The Mantha Declaration includes references to an alleged prior art Foundation Fieldbus webpage and certain exhibits that Mr. Crompton did not initially provide to BJC.⁶

In response to BJC's request, on March 17, 2008, Mr. Crompton provided the missing exhibits to Mantha's Declaration but he did not provide any alleged prior art documents (the letter from Mr. Crompton dated March 17, 2008 is attached hereto as Reference 4). In his letter, Mr. Crompton also pointed BJC to the Foundation Fieldbus webpage. Mr. Crompton provided no references to other webpages or documents that might show the existence of prior art bioreactor control systems. In addressing the issue of providing prior art references, he explained that although BJC has a duty of disclosure to the USPTO, his current clients are subject to no such obligation: "[a]s we do not share these same obligations to the PTO, we decline at this time to provide you with additional material."7

The undersigned printed the single referenced Foundation Fieldbus webpage and certain other webpages that are accessible from the Foundation Fieldbus webpage (referred to collectively as the "Foundation Fieldbus Webpages" and attached hereto as Reference 5). In this IDS, BJC submits all the material provided by Mr. Crompton and the above-described Foundation Fieldbus Webpages. The undersigned and BJC will continue to provide to the USPTO, in each of the '079 and '168 applications, any additional material references, as well as any other documents it receives from Mr. Crompton and Finesse regarding this matter.

ANALYSIS OF MANTHA'S AND WARREN'S DECLARATIONS П.

Mantha's inventorship claims rely on his assertions that BJC had no interest or part in developing a bioreactor control system until after West and Mantha built and demonstrated a BioNet® prototype.8 For nearly three years Mantha has made these assertions to BJC. Indeed, Mantha and West have declared numerous times that they developed BioNet® on their own (spare) time, without assistance from BJC but instead with Caltrol's support, and BJC had no interest or participation in BioNet® until after they demonstrated BioNet® to Amgen in March, 2003.9

⁶ http://www.fieldbus.org/index.php?option=com_content&task=view&id=45&Item=195. Decl. Mantha ¶ 51.

⁷ Letter from Mr. Crompton to Dr. Joseph Reisman dated March 17, 2008, attached hereto as Reference 4.

⁸ See, e.g., the West IDS.

⁹ See, e.g., BJC's May '07 IDS Reference 2 ¶¶ 10-13, 19, 26, 27; Reference 3 ¶¶ 9-12 and 16.

In the May '07 IDS, BJC provided documents contemporaneous with developing BioNet[®] in house in 2002. These documents show the allegations in Mantha's and West's more recent declarations to be false. Specifically the contemporaneous documents show: (i) BJC was developing BioNet[®] in 2002; (ii) West worked for BJC and for BJC's benefit to develop and the market BioNet[®] from 2002-2005; and (iii) BJC paid Caltrol for its help in assembling a BioNet[®] prototype, including all work performed by Caltrol and its employees/contractors, including Mantha. BioNet[®] was BJC's project from its conception.

The recent Mantha Declaration appears to be responsive to BJC's May '07 IDS. Specifically, the Mantha Declaration includes new statements that try to explain away facts shown by the documents in the May '07 IDS. Mantha now admits that West and BJC developed BioNet in 2002. He admits that in 2002 West worked for BJC to create BioNet[®] for BJC's benefit. ¹¹ However, Mantha does not offer any reconciliatory explanation of West's gross misrepresentations. Instead, Mantha blames his previous false statements on ex-Finesse employee West, asserting that West never informed him of BJC's BioNet development project. ¹² Mantha explains that *he* didn't know of BJC's in house bioreactor development project, and *he* had never heard anyone mention Stella until he read BJC's May '07 IDS. ¹³ Mantha has thus defined his position. For the Mantha Declaration and his inventorship claims to have any credibility requires that (i) Mantha was never informed of Stella, and (ii) Mantha had no knowledge of BJC's in house bioreactor control system development activity conducted in late 2002 and early 2003.

BJC submits contemporaneous documents herewith that undermine Mantha's Declaration. Briefly, the documents establish that (1) BJC and the undersigned satisfied their disclosure obligations and provided to the USPTO all the materials received from Mr. Crompton; (2) Mantha's assertion that he never heard of BJC's "Stella" development project is <u>false</u> because in November, 2002, West *himself* informed Mantha of BJC's ongoing in house project Stella and that he (West) was leading a team for BJC in this development effort; (3) there is no credible basis in Mantha's Declaration that he did anything other than help

¹⁰ See, e.g., the May '07 IDS References 7-14; West IDS, Decl. West ¶ 13.

^{11 &}quot;Mr. West created BioNet for BJC's Benefit." Decl. Mantha ¶ page 8 lines 4-5.

¹² "If other BJC employees were in fact contributing to the BioNet product, Mr. West never mentioned it..." Decl. Mantha ¶ 45.

¹³ E.g., see Decl. Mantha ¶¶ 15, 44.

reduce BJC's bioreactor control system to practice; (4) the Foundation Fieldbus Website shows a commercially available digital Foundation Fieldbus network that can be used as one of the communication networks in the claimed invention, which is exactly what BJC itself discloses in its patent application; and (5) the Warren Declaration adds little, if any, credible support for Mantha's inventorship claims.

1. BJC Submitted All The Non-Confidential "Mantha Materials" To The USPTO In Conformance With Its Duty Of Disclosure

Mantha alleges that BJC and the undersigned failed to disclose certain documents to the UPSTO, and such misrepresentations led to a piecemeal and misleading analysis of Mantha's inventorship contributions. For "proof," Mantha alleges "FI000151 [sic] was shown to KMOB on August 1, 2006; however, KMOB and BJC chose not to include it in either IDS that BJC submitted to the USPTO."¹⁴ Mantha also alleges "FI000205-207 [sic] was also shown to KMOB on August 1, 2006; however, again BJC and KMOB chose not to disclose these documents to the USPTO."¹⁵

These statements are false. The undersigned analyzed and submitted documents FI0000151 and FI0000205-207, along with all of the "Mantha Materials" that did not contain confidentiality information, to the USPTO in the Oct. '06 IDS. On October 30, 2006, BJC informed Mr. Crompton of its submission and sent him a copy of the Oct. '06 IDS via email and Federal Express; therefore Mr. Crompton knows that BJC submitted this material to the USPTO. ¹⁶ Furthermore, the Patent Application Information Retrieval System ("PAIR") shows that the USPTO received documents FI0000151 and FI0000205-207 (and the rest of the Mantha Materials) as evidenced by a Mail Room Date of 10-23-06. Accordingly, Mantha and Mr. Crompton either knowingly included these false statements in Mantha's Declaration, or the statements were included in Mantha's Declaration without verifying their accuracy.

As previously described in the Oct. '06 IDS, documents FI0000151 and FI0000205-207 do not support Mr. Mantha's inventorship claims. Document FI000151 is correspondence from Mr. Mantha (ATS) to Larry West (then a BJC employee) offering its

¹⁴ Decl. Mantha page 7, Footnote 5.

¹⁵ Decl. Mantha page 7, Footnote 6.

¹⁶ This correspondence is submitted herewith as Reference 6 (email) and Reference 7 (letter).

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services to support BJC's existing BioNet[®] project.¹⁷ Document FI0000151 is not dated. However, its content indicates it was generated after Mantha began working for ATS, while ATS was not formed until *after* BJC's prototype was demonstrated in March, 2003. Therefore the FI0000151 document is too late to show Mantha's conception of the claimed subject matter. Documents FI000205-207 include correspondence dated November 18, 2003, regarding marketing and configuring BioNet[®] systems for various clients. Neither Mantha or Mr. Crompton have reasonably explained how these documents illustrate conception. The documents are not contemporaneous with the conception of the claimed subject matter or the timeframe when BJC was building its prototype, and do not show that Mantha contributed to the subject matter of the pending claims in the BJC Applications.

2. Mantha Knew That West and BJC Were Developing A Bioreactor Control System In House At BJC In A Project Called Stella

West's allegations regarding BJC's non-interest and non-involvement are inconsistent with BJC's May '07 IDS. Attempting to distance himself from the former Finesse employee, Mantha blames West for not telling him that BJC was, in fact, actively developing BioNet[®] in house. Mantha insists he did not know of BJC's in house development project Stella. ^{18,19} With the credibility of his story (and inventorship claims) at stake, Mantha now states (i) he was never informed of Stella, and (ii) he had no knowledge of BJC's in house bioreactor control system development activity conducted in late 2002 and early 2003.

These statements are inconsistent with the documents. As illustrated in an e-mail dated November 13, 2002, <u>West himself</u> informed Mantha that BJC was developing a bioreactor control system and "[t]he in house name of this project here at Broadley-James is 'Stella.'"²⁰ While "forgetting" a particular project name (even one so memorably named "Stella") might be explained away by claiming to have an awfully poor memory, Mantha's

¹⁷ "Here is a list of services Advanced Tech Solutions (ATS) is prepared to provide for the support the [sic] BioNet project." FI0000151

¹⁸ "If other BJC employees were in fact contributing to the BioNet product, Mr. West never mentioned it..." Decl. Mantha ¶ 45.

¹⁹ "Prior to reading BJC's IDS, I do not recall any mention of an internal BJC project known as Stella." Decl. Mantha FN 7.

²⁰ As evidenced by a contemporaneous email dated November 13, 2002, from West to Mantha (attached hereto as Reference 8) stating "[t]he in house name of this project here at Broadley-James is 'Stella'. I have assembled

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failure to "recall" that BJC developed BioNet[®] in an "in house" project is simply not believable. The truth of West's contemporaneous email speaks for itself: BJC developed its bioreactor control system (BioNet[®]) in house during 2002 under a project called "Stella," and BJC employee West was the head of a BJC bioreactor control system team.²¹ Indeed, Mantha *knew* of Stella and *knew* BJC was developing a bioreactor control system in November, 2002. Mantha intentionally lied in his declarations. The e-mail shows Mantha's inventorship story has no basis and his declaration has no credibility.

3. Mantha's Declaration Merely Supports That He Helped Assemble A Prototype Of BJC's Bioreactor Control System

Mantha's Declaration includes numerous assertions regarding his inventorship contribution. He claims, for example, "I made an inventive contribution to 'everything that is claimed in both Applications," and "I was involved in all aspects of developing the BioNet® product and I should have been named as a co-inventor on all claims." Mantha alleges he conducted the vast majority of his development on BioNet® at Caltrol during late 2002 and early 2003, and continued developing BioNet® at ATS as evidenced by documents FI0000151 and FI000205-207. Mantha also asserts "my most critical aspect of my inventorship claim is that I designed and engineered that prototype." And he further asserts "it was my skills, training and experience, and those of the Caltrol employees and contractors I supervised, that allowed the BioNet® concept to be reduced to practice." Mantha makes many more assertions that essentially allege that he invented, designed and built every aspect of BJC's prototype.

As discussed above, Mantha's Declaration is inconsistent with the documents. His inventorship allegations completely rely on a false foundational story that Mantha created BioNet® without any BJC involvement.

two teams, one for the Vessel Hardware (i.e. glass jar, baffles, condensators, etc...) and the other for the System Aspect (i.e. pumps, meters, control logic, etc...)."

²¹ Reference 5.

²² Decl. Mantha ¶¶ 22 and 21. (emphasis in original quotes)

²³ Decl. Mantha ¶ 44.

²⁴ Decl. Mantha ¶ 29.

²⁵ Decl. Mantha ¶ 26.

²⁶ Decl. Mantha ¶ 27.

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Neither Mantha, nor Finesse nor West, have provided any corroborating evidence other than West's bare allegations. Indeed, Mantha did not produce a single document that shows his alleged conception and development of BioNet[®] or that illustrates he conceived of subject matter claimed in the BJC Applications. The undersigned and BJC have found no such documents that show Mantha conceived of the claimed subject matter. Mantha now admits there are no such BJC documents in his possession, custody or control, and he admits (not surprisingly) that there are no documents showing his written plans or designs for BJC's prototype.²⁷

Mantha did not and could not have "conceived" of BioNet[®] as he now alleges. Mantha states that he developed the vast majority of BioNet[®] while he was working on BJC's prototype at Caltrol, starting about November 2002.²⁸ This was after BJC conceived of BioNet[®] and after BJC began developing BioNet[®] in house.²⁹ Mantha worked at ATS sometime after March, 2003. Accordingly, any of Mantha's work at ATS post-dates BJC's in house bioreactor development project and BJC's benchtop bioreactor white paper (December 2002), and therefore it also cannot support his general allegations of conception.

Conception is the touchstone of inventorship.³⁰ Mantha's bare allegations do not show "conception" of the subject matter claimed in the BJC Applications.³¹ All the documents analyzed show he helped reduce BJC's invention to practice while he worked for Caltrol. Mantha's work with West in building BJC's prototype does not support inventorship claims because "one does not qualify as a joint inventor by merely assisting the actual inventor after conception of the claimed invention."³² In fact, "[a]n inventor may use the services, ideas and aid of others in the process of perfecting his invention without losing rights to his patent."³³ When evaluated as a whole, all the contemporaneous documents support that Mantha worked for Caltrol and assembled BJC's prototype, nothing more.

 $^{^{27}}$ Decl. Mantha ¶¶ 48 and 26.

²⁸ Decl. Mantha ¶ 44.

²⁹ See May '07 IDS including References 7-10.

³⁰ See Burroughs Wellcome Co. v. Barr Laboratories, Inc., 40 F.3d 1223, 1227 (Fed. Cir. 1994).

³¹ "Because it is a mental act, courts require corroborating evidence of a contemporaneous disclosure that would enable on skilled in the art to make the invention." Id. at 1228.

³² See Sewall v. Walters, 21 F.3d 411, 416 (Fed. Cri. 1994); Shatterproof Glass Corp. v. Libbey Owens Ford Co., 758 F.2d 613 (Fed. Cir. 1985).

³³ Shatterproof Glass Corp., 758 F.2d at 624.

Mantha specifically asserts that he is an inventor because he built a communication system with a feedback loop:

I achieved this functionality in the BioNet product by choosing components, which, when linked according to my designs, were capable of communicating information in the manner claimed in the Patent Applications. Specifically, I procured the appropriate digital control and monitoring system components, connected Delta V software and hardware via specific electrical circuits to create feedback loops, and then had Mr. Randy Warren program Delta V to that it could control the various components so that they exchanged information over a communication network and performed the tasks claimed in the BJC applications (e.g., responded to data, adjusted conditions in the bioreactor vessel.³⁴

Again, Mantha's mere allegations, without a supporting document, are insufficient, particularly in light of his misrepresentations. Even if Mantha's statements were true, his actions illustrate only prototype assembly, not conception. Merely procuring known components and connecting Delta V compatible components to make a feedback loop is not inventive. Mantha himself admits this later in his declaration.³⁵ Mantha's alleged choice of communication components in assembling BJC's prototype does not make him an inventor, nor does merely providing materials and suggestions to an inventor.³⁶ Mantha did no more than a skilled salesman would do in explaining how his employer's product could be used to meet a customer's requirements.³⁷ Mantha's alleged actions in assisting West to select components and derive information for BJC's prototype does not alter the state of West's status of the sole inventor of the BJC Applications or affect the patentability of the subject matter claimed in the BJC Applications.³⁸

³⁴ Decl. Mantha ¶ 27.

³⁵ Decl. Mantha ¶¶ 49-54.

³⁶ See *Hess v. Advanced Cardiovascular Systems, Inc.*, 106 F.3d 976 (Fed. Cir. 1997), cert. denied, 520 U.S. 1277 (1997) (affirming there was no conception, and therefore no co-inventorship based on explaining to an inventor the state of the art and supplying a product for the inventor to use in the invention).

³⁷ "As a technology Consultant at Caltrol, my primary responsibility was to sell process control equipment." Decl. Mantha ¶ 36.

³⁸ "More than 140 years ago the Supreme Court, in holding that Samual Morse's disclosure with scientists in connection with his invention of the telegraph did not alter his status of sole inventor of that device, stated 'No invention can possibly be made, consisting of a combination of different elements ... without a thorough knowledge of the properties of each of them, and the mode in which they operate on each other. And it can make no difference, in this respect, whether [the inventor] derives his information from books, or from conversation with men skilled in the science. If it were otherwise, no patent, in which a combination of different elements is used, could ever be obtained." *Hess*, 106 F.3d at 981, quoting *O'Reilly v. Morse*, 56 U.S. 62, 111 (1853).

4. BJC Disclosed In The BJC Applications That A Foundation Fieldbus Network Can Be Used To Practice The Invention

After asserting that he invented BioNet® for nearly three years, Mantha now changes course and asserts the BJC Applications do not recite a patentable invention.³⁹ Mantha alleges "[a]t the time Mr. West and I developed the BioNet product, the technology used in bioreactor control and monitoring systems was digitally enabled to accomplish the same 'communications,' 'control' and 'networking' tasks recited in the Patent Applications."⁴⁰ Mantha indicates a Foundation Fieldbus Interface and its related technology is prior art to the subject matter claimed in the BJC Applications. In support of this assertion, he alleges Foundation Fieldbus "is an open, non-proprietary architecture that process automation industries use in their control and instrumentation systems to enable each device or component used in the system to communication via an all-digital, two-way communication system."⁴¹

Mantha references a Foundation Fieldbus website he last checked on September 6, 2007 as support for his allegations.⁴² Mantha apparently reasons "the BioNet product utilizes this established infrastructure" and "[t]he Patent Applications claim matter that is inherent in Foundation Fieldbus technology."⁴³ Mantha also alleges "I had seen numerous bioreactors control and monitoring system use the same digital components that we used in the BioNet product to transmit and receive data from the bioreactor vessels, monitoring systems, and control systems."⁴⁴ Mantha concludes "the methods and systems claimed in BJC's Patent Applications were already widely in use at the time that BJC filed the '079 and '168 Applications."⁴⁵ Except for a single Foundation Fieldbus website, Mantha discloses no other websites, alleged prior art bioreactor control systems or documents to support his new allegations.

³⁹ Decl. Mantha ¶ 49-54.

⁴⁰ Decl. Mantha ¶ 50.

⁴¹ Decl. Mantha ¶ 51.

⁴² http://www.fieldbus.org/index.php?option=com_content&task=view&id=45&Itemid=195 Decl. Mantha ¶ 51.

⁴³ Id.

⁴⁴ Decl, Mantha ¶ 52.

⁴⁵ Decl. Mantha ¶¶ 49-54.

Of course, Foundation Fieldbus existed when BJC developed its bioreactor control system and wrote the BJC Applications. The BJC Applications describe an illustrative embodiment that include a commercially available Foundation Fieldbus as a network, and disclose that it can be purchased from Emerson Process Management in Austin, Tex.⁴⁶ The BJC Applications disclose that a Foundation Fieldbus network can be used to transmit pH, dissolved oxygen ("DO"), and temperature information from a utility tower to a controller, and it can be one of three networks that communicate information between a utility tower and a controller in BJC's bioreactor control system.⁴⁷⁻⁴⁸ Mantha disclosure of Foundation Fieldbus functionality is nothing more than what BJC itself has already disclosed. As illustrated at least by the pending claims themselves, the subject matter of the BJC Applications does not rely or require using a Foundation Fieldbus network (or any other particular type of communication network).

Despite his broad assertions, Mantha's only reference to alleged prior art is the Foundation Fieldbus website. He provides no information on bioreactor systems similar to those described and claimed in the BJC Applications and no contemporaneous material in support of his bare allegations. Accordingly, the undersigned cannot analyze specific technical aspects of Mantha's other statements regarding prior art or determine their credibility. Mantha, Finesse, or Mr. Crompton have provided no other "prior art" material to BJC and the undersigned. Tellingly, Mr. Crompton states that his current clients have no disclosure obligation to the USPTO.⁴⁹

Mantha appears to suggest that BJC is claiming patent rights in Foundation Fieldbus technology because the BJC Applications "claim matter that is inherent in the Fieldbus technology." Obviously, BJC makes no such claim. Ironically, this may explain Mantha's mis-perception that his alleged involvement with building BJC's prototype and reducing BJC's invention to practice constitutes grounds for inventorship claims.

The undersigned collected a printed copy of the Foundation Fieldbus website page that Mantha specifically referenced, and certain additional material available via the website, and

⁴⁶ BJC Application Pub. No. US 2005/0112542 A1 (U.S. Application No. 10/723,168) ¶ 37.

⁴⁷ See e.g., US 2005/0112542 ¶¶ 37, 40, 41, 42, 49, 50, 54, and Figure 5 (U.S. Application No. 11/057,079).

⁴⁸ BJC Application Pub. No. US 2005/0112542 A1 (U.S. Application No. 10/723,168) ¶ 37.

⁴⁹ Letter from Mr. Crompton to Dr. Joseph Reisman dated March 17, 2008, attached hereto as Reference 4.

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submits such material in this IDS as Reference 5. As indicated by its copyright marking, the Foundation Fieldbus website was updated at least as recent as 2006. The Foundation Fieldbus website generally describes a digital communication system that can be used to connect many types of digital control devices. This website discloses general aspects of digital communication and does not suggest or teach the particular limitations of the claims pending in the BJC Applications. While the undersigned has not reviewed every possible webpage that is linked, associated and/or accessible from the Foundation Fieldbus website using their provided search tool revealed zero (0) hits for the search term "bioreactor." Similarly, an ad hoc website search revealed descriptions of general biotechnology applications that do not disclose subject matter claimed in the BJC Applications.

5. Warren's Declaration Do Not Support Mantha's Inventorship Claims

Warren's Declaration provides no support for and does not corroborate Mantha's inventorship claims. As illustrated by the above-described documents (and documents previously submitted by the undersigned), BJC developed its bioreactor control system in house and contracted with Caltrol to help build a prototype. Warren never mentions BJC's in house bioreactor development project. Thus, he apparently had no knowledge that BJC, in fact, had paid for and directed *all* the BJC prototype work. Warren's assertion that "it was clear to me that Mr. Mantha was at the technical and supervisory helm of the project" is inconsistent with Mantha's own admission that West was working for BJC and for BJC's interest in leading BJC's bioreactor control system development. While Warren's observations and opinions may be of interest, they are based upon what Mantha told him.

The undersigned notes that the Mantha and Warren Declarations are inconsistent with Mantha's allegations that he created the prototype without written plans.⁵¹ Warren alleges "Mr. Mantha created a number of plans and sketches for the prototype" and "Mr. Mantha provided Caltrol with a technical roadmap showing us how he could utilize existing process control components to construct a bioreactor control and monitoring system with Amgen's

⁵⁰ Decl. Mantha ¶ 51.

⁵¹ Decl. Mantha ¶ 26.

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desired design-characteristics and functionality.⁵² Warren does not provide copies of the referred to plans, sketches and roadmaps. The undersigned notes that the only "plans" that Mantha ever produced were drawn from BJC's prototype.53

In his declaration Warren confirms that Mantha began working on BJC's prototype in November 2002: "[a]fter working on a prototype for three or four months, Mr. Mantha and Mr. West showed the product to Amgen" (the Amgen demonstration occurred in early March, 2003).⁵⁴ This is consistent with the November, 2002 email sent to Mantha in which West informed him of BJC's ongoing in house bioreactor development project named Stella. Of course, as illustrated in previously submitted documents, BJC conceived of BioNet® and began its in-house development project much earlier.

III. CONCLUSION

This submission shows there no evidentiary basis to name Mantha as an inventor of the BJC Applications. Instead, the documents submitted herewith undermine Mantha's claim regarding his inventorship. Not surprisingly, neither Finesse, Mantha, or West have provided a single contemporaneous document showing Mantha conceived any subject matter claimed in Contrary to Mantha's assertions, BJC has conformed with its the BJC Applications. disclosure obligations and has provided all the material it received from Mr. Crompton/Finesse to the USPTO. Similarly, Warren's Declaration provides no support for Mantha's inventorship claims. Consistent with previous BJC submissions, Mantha at best helped reduce BJC's bioreactor control system to practice by assembling a prototype for BJC. Finally, Mantha's "disclosure" of the Foundation Fieldbus as alleged prior art is meaningless because BJC itself disclosed the Foundation Fieldbus network in the BJC Applications, and the Foundation fieldbus website does not appear to disclose prior art that is material to the patentability of the pending claims.

While the undersigned will continue to analyze all the material it receives from Finesse and will, of course, conform with its duty of disclosure to the USPTO, we consider this matter closed.

⁵² Decl. Warren ¶¶ 11 and 12.

⁵³ Decl. Mantha ¶ 26.

⁵⁴ Decl. Warren ¶ 16.

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The Commissioner is authorized to charge the fee set forth in 37 C.F.R. § 1.17(p) to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: May Z, Zoo

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